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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MRUGESH SHAH

Appeal 2011-001119
Application 10/776,711
Technology Center 1600

Before DONALD E. ADAMS, ERIC GRIMES, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods of making biosynthetic petroleum. The Examiner has rejected all of the claims as nonenabled, and some of the claims for including new matter. We have jurisdiction under 35 U.S.C. § 6(b). We affirm both rejections.

STATEMENT OF THE CASE

The Specification states that "[c]ertain microorganisms can produce petroleum from solid fossil fuels, including coal. . . . *See* International Patent

Application No. WO 0246446." (Spec. 1: 6-11.) "The genes from such microorganisms can be isolated and used to make a genetically engineered host with optimal characteristics" (*id.* at 2: 3-4).

The Specification states that the "invention also includes the making of hydrocarbons, including petroleum, from water or from elemental carbon, hydrogen and oxygen. . . . Again, genes from naturally-occurring bacteria which accomplish this conversion can be transfected to other hosts to optimize production." (*Id.* at 3: 1-5.)

Claims 1, 3, 9, 11-15, 17, and 18 are on appeal. Claims 1, 11, and 17 are representative and read as follows:

1. A method of converting (i) solid fossil fuels, or
(ii) oil tars obtained by distillation of coal, turf, grass, rubber, sapropel, sapropelites, slates, or wood, into biosynthetic petroleum, comprising the steps of:
a) isolating a starting microorganism capable of said conversion;
b) isolating from the starting microorganism the genes responsible for the conversion ability;
c) transfecting the genes into a host microorganism, and
d) combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into biosynthetic petroleum.

11. A method of converting carbon, hydrogen and oxygen into biosynthetic coal or biosynthetic petroleum, comprising the steps of:
(a) isolating a starting microorganism capable of said conversion;
(b) isolating from the starting microorganism the genes responsible for the conversion ability;
(c) transfecting the genes into a host microorganism; and
(d) combining the host microorganism with the carbon, hydrogen and oxygen under conditions suitable for the conversion of the carbon, hydrogen and oxygen into biosynthetic coal or biosynthetic petroleum.

17. A method of converting (i) solid fossil fuels, or (ii) oil tars obtained by distillation of coal, turf, grass, rubber, sapropel, sapropelites, slates, or wood, into biosynthetic petroleum, comprising the steps of:

a) obtaining a gene encoding a protein capable of said conversion;

b) transfecting the gene into a host microorganism, and

c) combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into biosynthetic petroleum.

I.

The Examiner has rejected claims 17 and 18 under 35 U.S.C. § 112, first paragraph, "for reciting new matter of 'obtaining a [singular] gene coding a protein capable of said conversion'" (Answer 7, alteration in original). The Examiner finds that the "original specification and original claims describe plural genes capable of said conversion, and not a singular gene capable of said conversion" (*id.*).

Appellant does not specifically address the new matter basis of the rejection but argues that the Specification enables claims 17 and 18 because "[t]he *Specification* does not have to provide any guidance for things readily available and well known to those of ordinary skill in the art" (Appeal Br. 19). In support of this position, Appellant points to an international patent application cited in the Specification,[1] Kurashov,[2] and Cohen[3] (*id.*).

We will affirm this rejection. The Specification states that the "invention relates to a method of making microorganisms capable of producing petroleum from coal [or other sources]. The method involves

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[1] WO 0246446 (Spec. 1: 8-9).
[2] Kurashov et al., RU 2180919 C1 (Mar. 27, 2002).
[3] Cohen et al., *Degradation of Coal by the Fungi Polyporus versicolor and Poria monticola*, 44 APPL. ENV. MICROBIOL. 23-27 (1982)

isolating the *gene sequences* responsible for such production . . . then transfecting these *gene sequences* into other host cells." (Spec. 2: 6-11, emphasis added.) Appellant has not pointed to any description in the Specification of a process of converting a solid fossil fuel or oil tar into biosynthetic petroleum using an enzyme encoded by a single gene.

Nor has Appellant provided evidence that the Specification's description of converting a solid fossil fuel or oil tar into biosynthetic petroleum through the actions of multiple enzymes encoded by different genes would have been recognized by those skilled in the art as a description of carrying out the conversion using a single enzyme encoded by a single gene. We have considered the prior art cited by Appellant but conclude that the references do not show that the Specification describes the method of claims 17 and 18.

II.

Issue

The Examiner has rejected claims 1, 3, 9, 11-15, 17, and 18 under 35 U.S.C. § 112, first paragraph, for lack of enablement (Answer 8). The Examiner finds that petroleum is "a complex mixture containing multiple components" (*id.* at 6) and therefore the claims are directed to "methods utilizing a transfected microorganism to produce synthetic products being or resembling the variable and complex mixtures of petroleum" (*id.* at 8-9).

The Examiner finds that achieving the claimed result would require "complex and multiple gene activities which are conversions of feedstocks into biosynthetic petroleum" (*id.* at 11) and that even the relatively simpler processes of producing ethanol or simple alkanes from biomass have

presented a variety of problems (*id.* at 9-11). The Examiner finds that an extremely large amount of experimentation would be required to identify and isolate the required genes and to express them properly to carry out the required conversions, "if in fact a single transfected microorganism were capable of the claimed conversions" (*id.* at 12).

The Examiner finds that the Specification provides no working examples and only general guidance with respect to molecular biological techniques (*id.* at 13) and that the prior art does not provide the guidance lacking in the Specification (*id.* at 14). The Examiner concludes that, although the level of skill in the art is high (*id.*), undue experimentation would be required to practice the full scope of the claimed method (*id.* at 15).

Appellant contends that the Examiner is incorrectly requiring that "the claims must be enabled for an industrial scale and commercially viable means of production" (Appeal Br. 9-12; Reply Br. 4-7), and that a proper *Wands* analysis supports enablement of the claimed methods (Appeal Br. 13-21). Appellant also contends that affirmative proof of enablement has been provided for claims 1 and 11 (*id.* at 21-28).

The issue with respect to this rejection is: Does the evidence support the Examiner's conclusion that the guidance provided by the Specification, combined with the state of the art, is inadequate to enable practice of the claimed method without undue experimentation?

Findings of Fact

1. We adopt the Examiner's factual findings regarding the *Wands* factors (Answer 8-14), with the exception noted below (FF 2).

2. The Examiner finds that the teachings of Van Hamme[4] relate to alkane production (Answer 10-11). The passages cited by the Examiner, however, relate either to degradation of hydrocarbons or to general research methods, not to synthesis of hydrocarbons by microorganisms.

3. The Specification discloses that application WO 0246446 discloses that certain microorganisms – specific strains of *Thiobacillus aquaesullis*, *Thiosphaera pantotropha*, and *Thoibacillu* [sic, *Thiobacillus*?] *thoioparus* – "can produce petroleum from solid fossil fuels" (Spec. 1: 4-18).

4. The Specification discloses that one technique for "isolating the gene sequences responsible for a particular function is subtractive hybridization" (*id.* at 3: 19-20), which "allows one to enrich for nucleic acid sequences present in one sample but absent, decreased, or altered in another sample" (*id.* at 3: 20-22). The Specification describes in general terms the process of cloning DNA using subtractive hybridization (*id.* at 4: 13 to 6: 4).

5. The Specification discloses that "genes capable of producing petroleum from fossil fuels" could be cloned by subtractive hybridization from "bacterial strains capable of such production, e.g., *Thiobacillus aquaesullis* 4255 and 389, *Thiosphaera pantotropha* 356, *Thiosphaera pantotropha* 2944, and *Thoibacillu* [sic] *thoioparus* 55 . . . (all of which are described in International Application No. WO 0246446)" (*id.* at 4: 3-8).

6. The Specification discloses that "[f]ollowing isolation of target sequences using subtractive hybridization, they could also be directly transfected into a host microorganism, using conventional techniques, to

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[4] Van Hamme et al., *Recent Advances in Petroleum Microbiology*, 67 MICROBIOL. MOL. BIOL. REV. 503-549 (2003)

attempt to produce a microorganism capable of producing petroleum from solid fossil fuels in a highly efficient, commercially viable manner" (*id.* at 6: 5-8).

Principles of Law

"The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *National Recovery Technols. Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed Cir. 1999).

> Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (citation omitted).

> [A] specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. . . . It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Id. (citation omitted).

Analysis

We agree with the Examiner that the guidance provided by the Specification, even when combined with the existing knowledge of those skilled in the art, is inadequate to enable a skilled worker to practice the full scope of the claimed methods without undue experimentation. The Examiner has provided extensive fact-finding to support his conclusion of nonenablement and (with the exception noted above) we agree with and adopt that fact-finding and the Examiner's reasoning (Answer 14-15) leading to the conclusion that the claims on appeal are not enabled by the Specification.

To summarize, claim 1 is directed to a generic method of converting solid fossil fuels (or oil tars) to biosynthetic petroleum by isolating a microorganism capable of doing so, isolating the relevant genes from that microorganism, transfecting them into another microorganism, and combining that microorganism with a solid fossil fuel (or oil tar). The Specification identifies three species of microorganisms that had been disclosed in the prior art as being capable of converting solid fossil fuels to biosynthetic petroleum (FFs 3, 5), and therefore suitable candidates for step a of claim 1. The Specification also identifies a prior art technique that "allows one to enrich for nucleic acid sequences present in one sample but absent" from another (FF 4) in preparation for cloning cDNA.

The Specification, however, provides no guidance whatsoever on carrying out the step of "isolating from the starting microorganism the genes responsible for the conversion ability" (claim 1, step b), which is of course the most difficult part of the claimed method: if the relevant genes have

been isolated, transfecting them into a host cell (step c) and contacting the host cell with a substrate (step d) would be routine.

When it comes to the critical "isolating" step of claim 1, the Specification provides no help to the skilled artisan. The Specification does not identify any specific starting material in solid fossil fuels that is changed during the conversion to petroleum, nor does it identify any of the end products in the resulting petroleum. The Specification does not identify any of the chemical reactions involved in the claimed conversion method, or any assay to use in identifying enzymes that catalyze such reactions. The Specification does not identify any specific enzymes that are involved in the conversion or any genes that encode such enzymes. The Specification does not even identify – does not, in fact, as much as hint or guess at – how many chemical reactions or enzymes are involved, or the number of "genes responsible for the conversion ability" that would have to be isolated and transfected into a new host in order to practice the method of claim 1.

In short, "[t]his specification provides only a starting point, a direction for further research," *Genentech*, 108 F.3d at 1366, rather than sufficient guidance to enable practice of the full scope of the claims without undue experimentation. In *Genentech*, "the specification [did] not describe a specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work." *Id.* at 1365. The court held that "when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot

be rectified by asserting that all of the disclosure related to the process is within the skill of the art." *Id.* at 1366.

Similarly here, the Specification does not disclose any of the genes that must be isolated from a starting microorganism to transfer to a new host, nor does it describe any of the activities of the enzymes encoded by those genes, or any of the chemical reactions catalyzed by the enzymes, or any assay conditions that can be used to detect the presence of such enzymes. Just as in *Genentech*, the Specification's near-total lack of guidance to direct those skilled in the art in practicing the critical step of the claimed method represents a failure to meet the enablement requirement of 35 U.S.C. § 112, first paragraph, that cannot be rectified by reliance of the knowledge of those skilled in the art.

Appellant argues that the Examiner is requiring enablement of the claimed method on a commercial or industrial scale, which is beyond the enablement required by § 112 (Appeal Br. 9-13, Reply Br. 4-7). This argument is unpersuasive. The Examiner's explanation of the rejection does not focus on the scale of production, and the Examiner has provided adequate evidence to support his conclusion that the Specification does not provide sufficient guidance to enable practice of the claimed method on any scale without the necessity of undue experimentation.

Appellant also argues that the state of the art is not as unpredictable as the Examiner asserts, in that "Zaldivar discloses several microorganisms capable of metabolizing lignocellulose derived sugars into bioethanol" (Appeal Br. 14). This argument is unpersuasive because the claimed method requires producing biosynthetic petroleum from solid fossil fuels, not

producing ethanol from lignocellulose. Zaldivar therefore does not relate to the state of the art of the claimed method.

Appellant also argues that Van Hamme does not support the rejection because one does not need to understand the enzymology of a gene product in order to use it (Appeal Br. 16) and that Van Hamme's "discussion of microbial alkane degradation metabolism . . . is still not a teaching of *making* a component of coal or petroleum" (*id.* at 18). These points, while valid, do not persuade us that the Examiner's rejection is not supported by the cited evidence as a whole or that Van Hamme in any way supports enablement of the claimed method.

Regarding step (b) of claim 1, Appellant argues that the Specification "identifies a subtraction hybridization/screening approach for isolating the genes" (Appeal Br. 23). Appellant acknowledges the Examiner's position that "there is no guidance on the substep of . . . identification of responsible genes" (*id.*) but asserts that this "overlooked Applicant's supplied expression cloning paper, which establishes that this type of molecular biology work was routine, in the extreme, at the filing date of the application" (*id.* at 23-24).

This argument is also unpersuasive. Appellant does not identify the "supplied expression cloning paper" that supposedly provides the critical guidance required to enable the claimed method. While expression cloning in a general sense was a well-known technique by 2003, successfully cloning a given gene by expression cloning requires knowledge of the target gene that is sought and an assay to distinguish recombinant clones expressing the desired gene from those expressing other genes. As

discussed above, the Specification provides no guidance at all on what genes must be isolated and transfected into a recombinant host in order to practice the claimed method, or the activities of the enzymes encoded by those genes, or appropriate assays to determine the expression of those enzymes. A reference discussing expression cloning generically would provide almost no help in cloning the specific genes required to practice the claimed method.

With regard to claim 11, Appellant argues that the state of the art enables the claimed method "by analogy to the evidence and explanation for claim 1" (Appeal Br. 26). This argument is unpersuasive for the reasons discussed above.

Appellant also argues that "[t]he Dennis reference further demonstrates the enabling state of the art for" claim 11's steps a) and b) (*id.* at 26-27) and that "the success of LS9 in making biosynthetic petroleum is a direct example of applying synthetic biology to create transgenic microorganism hosts" (*id.* at 27).

This argument is also unpersuasive. Neither Dennis (Appellant's Evidence Appendix, Exhibit J) nor the LS9 references (*id.*, Exhibits I, K, L, and M) show the state of the art as relevant to claim 11. Claim 11 is directed to a "method of converting carbon, hydrogen and oxygen into biosynthetic coal or biosynthetic petroleum." The Specification makes clear that the claim is directed to "making of hydrocarbons, including petroleum . . . from *elemental* carbon, hydrogen and oxygen" (Spec. 3: 1-2, emphasis added), not from any old feedstock that contains those elements. Claim 11 therefore requires the conversion of, for example, charcoal, hydrogen gas (H_2), and

oxygen gas (O_2) into biosynthetic petroleum or biosynthetic coal using a recombinant microorganism.

Dennis discloses an enzyme that forms a hydrocarbon by removing carbon monoxide from a fatty aldehyde (Dennis 5306, abstract). LS9 produces "petroleum-like fuels" (Plenty[5] 2) using "bacteria that eat almost any type of plant . . . digest it, and convert it into 'fuel'" (*id.* at 1). Thus, the references cited by Appellant do not provide support for the position that microorganisms that convert elemental carbon, hydrogen, and oxygen were known in the art.

Appellant's argument with regard to claims 17 and 18 (Appeal Br. 19-20) has been addressed above. Appellant's argument for enablement of these claims is unpersuasive for the same reason.

Conclusion of Law

The evidence supports the Examiner's conclusion that the guidance provided by the Specification, combined with the state of the art, is inadequate to enable practice of the claimed method without undue experimentation. Claims 3 and 9 fall with claim 1, and claims 12-15 fall with claim 11, because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(vii).

SUMMARY

We affirm the rejection of claims 17 and 18 under 35 U.S.C. § 112, first paragraph, based on new matter. We affirm the rejection of claims 1, 3,

[5] Evidence Appendix, Exhibit M

9, 11-15, 17, and 18 under 35 U.S.C. § 112, first paragraph, based on nonenablement.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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